

VERMONT BUPRENORPHINE
PRACTICE GUIDELINES

August 1, 2003
Rev. Oct. '05

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Vermont Buprenorphine Practice Guidelines

On October 17, 2000, “The Children’s Health Act of 2000” (HR 4365) was signed into federal law. Section 3502 of that Act sets forth the “Drug Addiction Treatment Act of 2000” (DATA). This legislation is of particular interest to state medical boards because it provides for significant changes in the oversight of the medical treatment of opioid addiction. For the first time in almost a century, physicians may treat opioid addiction with opioid medications in office-based settings. These opioid medications, Schedules III, IV, and V opioid drugs with Food and Drug Administration (FDA) approved indication for the treatment of opioid dependence, may be provided to patients under certain restrictions. This new treatment modality makes it possible for physicians to treat patients for opioid addiction with these Schedules III-V narcotic controlled substances specifically approved by the FDA for addiction treatment in their offices without the requirement that they be referred to specialized opioid treatment programs (OTP’s) as previously required under federal law. Physicians who consider office-based treatment of opioid addiction must be able to recognize the condition of drug or opioid addiction and be knowledgeable about the appropriate use of opioid agonist, antagonist, and partial agonist medications. Physicians must also demonstrate required qualifications as defined under and in accordance with the “Drug Addiction Treatment Act of 2000” (DATA) (Public Law 106-310, Title XXXV, Sections 3501 and 3502) and obtain a waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA), as authorized by the Secretary of HHS.

The Vermont State Medical Board is obligated under the laws of the State of Vermont to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioids, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians must be diligent in preventing the diversion of drugs for illegitimate and non-medical uses.

Practitioner Requirements for a Waiver:

Must be licensed in the state of Vermont plus meet one or more of the following:

- ABPN Added Qualification in Addiction Psychiatry
- Certified in Addiction Medicine by ASAM
- Certified in Addiction Medicine by AOA
- Investigator in buprenorphine clinical trials
- Has completed 8 hours of training provided by ASAM, AAAP, AMA, AOA, APA or other designated organizations. Web sites are: www.aaap.org or www.apa.org.
- Training/experience as determined by state medical licensing board
- Other criteria established through regulation by the Secretary of Health and Human Services
- Physicians who are seeing patients under the DEA number of an Opiate Treatment Program do not have to apply for the waiver, nor are they required to take the 8 hour training course.

Once training is completed, the physician registers at SAMHSA (<http://buprenorphine.samhsa.gov/howto.html>) to obtain a waiver. A certificate will be sent to the physician with a special DEA license number amendment. This must be put on all prescription. Prescribing without this number is a violation.

The “qualifying physician” must have the capacity to refer patients for appropriate counseling and other services that might be needed in conjunction with buprenorphine treatment. These include:

- Different levels of chemical dependency treatment services¹
- Psychiatric consultation
- Consultation for medical co-morbidities²
- 12 Step program
- Staff and patient education/training program³
- Urine screening, either onsite or in conjunction with certified laboratory
- Coverage with knowledge and experience using buprenorphine and office policies and procedures
- Medication security and storage

No more than 30 patients to be treated at one time per physician

As of July 2005 Congress passed legislation to adjust the 30-patient limit for physician group practices that dispense buprenorphine in an office-based setting to individuals with opioid dependence. Now, each physician in a group practice will be allowed to treat 30 patients with buprenorphine

Buprenorphine

Buprenorphine is used for both long-term maintenance and for medically supervised withdrawal/detoxification from opiates. It has been found to be safe and effective in minimizing withdrawal symptoms as well as blocking the effects of illicit opiates. It is a partial opioid agonist: at low doses, it acts as an agonist and at high doses as either an agonist or antagonist depending on the circumstance. Unlike morphine or other full agonist, Buprenorphine's effects are not linear with increasing doses and it exhibits a "ceiling effect". The significance of the ceiling effect is on the respiratory system and that an individual who takes too much is less likely to die from overdose.

Buprenorphine Preparations Available:

Both of the following are pill preparations that are dissolved sublingually.

- Subutex: Mono-therapy containing only buprenorphine. Available from pharmaceutical house in small supply to be kept in MD's offices.
May be used for induction but is not necessary for this.
- Suboxone: Combination therapy. This preparation contains a combination of buprenorphine and naloxone. The naloxone has been added to avoid the possibility of diversion and abuse IV. This is the recommended preparation for induction, detox and maintenance.

Patient Assessment/Screening:

Treatment Setting:

Office Based Treatment

The initial screening for addiction should consist of a combination of interviews, objective screening instruments and laboratory evaluations. (see attached examples of screening tools)

Within practice care:

Single Practitioner with training and flexibility to provide clinical evaluation, buprenorphine induction, maintenance and follow up including consultation and referrals as needed with Primary Care Providers and Medical Specialists. A practitioner may be able to provide all of the services on their own ie. An addictions psychiatrist with Buprenorphine training.

Integrated network of care: "Hub and Spoke Model"

Definition: A treatment network that consists of providers with necessary training and education to provide a continuum of services for opiate dependent patients.

The Vermont Department of Health, Division of Alcohol and Drug Abuse Programs (ADAP), proposes that "Hubs" of services be established in the various regions of the state. These Hubs would provide patient entry into available services through assessment, buprenorphine induction and referrals back to "Spokes" i.e., primary care physicians for maintenance once stabilized, as well as to substance abuse and dual diagnosis treatment. Referral for entry into a Hub may come from a Primary Care Physician, Psychiatrist, Counselor, Emergency Room or the patient may self refer. There may be a certain population of patients who receive all of their services in such a Hub

depending on the availability of services in an area or specific patient needs. Representation from ADAP will be available for consultation for all of the state providers especially as more appropriate patients are identified and started in treatment. Please note that one such “hub and spoke model” is in the process of being piloted in the Central Vermont area using Central Vermont Substance Abuse Services as the primary Hub. Details about this will be available at a later date.

Confidentiality and flow of information will be particularly challenging and important to be certain that all treatment providers are aware of specific issues that pertain to a given patient as well as the type of specific treatment that is being proposed. All information sharing must conform to current 42cfr part2 and HIPPA standards for a release of information form

Opiate Treatment Program

Recent legislation as determined that buprenorphine in either the single (Subutex) or combination form (Suboxone) can be given at OTPs with the same exact regulations for methadone (42CFR part 8). This includes the take-home schedule: *buprenorphine is to be dispensed from the window and no prescriptions are given*. Due to the long acting nature of buprenorphine, dosing need only occur two to three times per week. Buprenorphine will be part of the program’s DEA’s registration, not the individual physician’s, so that physicians working in OTPs do not have to seek a waiver or take the 8 hour training. The program is exempt from the 30 patient limit.

Exceptions for take homes and other issues such as a “clinic closed” day can be submitted for buprenorphine as has been the case with methadone.

Link for the exception form:

<http://www.samhsa.gov/centers/csat/content/dpt/Exception168Final.pdf>

Link to get Instructions for completing the exception form:

<http://www.samhsa.gov/centers/csat/content/dpt/instructions168Final.pdf>

Screening/Intake:

1. Medical history with attention paid to liver and cardiac status and medications
2. Psychiatric history with attention to current compliance with medications
3. Substance abuse history and treatment history to identify if patient was ever on Buprenorphine and to insure that patient is not currently on Methadone but meets criteria for Opiate Dependence (see DSM-IV-TR based criteria)
4. Social, work, and family circumstances history
5. Physical exam, mental status exam
6. Lab screening for ALT, AST, Hep B,C, HIV, Gonorrhea, Chlamydia, Syphilis, TB test
7. Urine screen (witnessed) with attention to opiates (including Methadone) and benzodiazepines.
8. If urine is negative for opiates (which may occur with synthetic opiates) you will need to rely on evidence of IV puncture marks on the skin and evidence of withdrawal symptoms in various stages such as:
 - Runny eyes, sniffing, yawning, tremor, sweating, gooseflesh, vomiting, abdominal cramps, muscle aches, pupil dilation. A CINA scale can be very useful (see enclosed)

9. In some cases the use of 1 cc of naloxone (Narcan) (0.4 mg/ml) must be injected subcutaneously and the patient observed for up to 30 minutes for evidence of precipitated withdrawal, which would aid in diagnosing dependence. Naltrexone (ReVia) would not be used in this circumstance due to the protracted withdrawal syndrome that it causes.
10. There are some circumstances when the patient has been detoxed from opiates and will show no evidence of withdrawal symptoms but is presenting for treatment due to high risk of using again despite multiple treatment attempts. Examples would be released from prison, voluntary or involuntary withdrawal from opiates, etc. Consultation with a substance abuse counselor or addiction specialist is encouraged in these cases.
11. Once this is completed, a consent form and a contract should be reviewed and signed by the patient and the physician (see enclosed). One copy goes in the chart and one goes to the patient. A copy of the contract should be sent to the pharmacy.
12. Release of information forms should be completed for the Substance Abuse Counselor and the pharmacy that will be dispensing. Any other agencies such as the VNA, SRS, Psychiatrist, referring treatment center, etc, should also have releases signed and placed in the chart.

Factors that indicate that a patient is LESS likely (not hard and fast “rules”) to be an appropriate candidate for office based buprenorphine treatment

Dependence of high doses of benzodiazepines, alcohol, or other CNS depressants

Significant psychiatric co-morbidity

Active or chronic suicidal or homicidal ideation or attempts

Multiple previous treatments and relapses

Non-response to buprenorphine in the past

High level of physical dependence (risk for severe withdrawal)

High relapse risk

Pregnancy

Current medical conditions that could complicate treatment

Poor support systems

Patient needs cannot be addressed with existing office-based resources

Buprenorphine- Induction:

1. Prescriptions should be written for one day at a time. * The special DEA number must be written on the prescription.
2. Inductions should begin early in the week, unless the office is open 7 days a week.
3. Patient takes the script to the pharmacy and brings it back to the office.
4. Patient's last reported use should have been at least 6 hours prior to induction.
5. MAKE SURE THAT THE PATIENT IS NOT ON METHADONE.
6. Patient takes the tablet and crushes it in the mouth and then lets it dissolve under the tongue.

Patients **NOT** physically dependent on opioids ie coming out of incarceration or otherwise high risk for relapse:

First dose: 2mg sublingual buprenorphine

Monitor for 2+ hours

Gradually increase the dose over several days

Patients dependent on **SHORT ACTING** opioids

Instruct patient to abstain from any opioid use for 12-24 hours so that they are in mild withdrawal at time of first buprenorphine dose.

Note: If patient is not in withdrawal, have them wait and reassess, revisit their use or abstinence over past 12-24 hours or return another day

First Dose: 2mg sublingual Suboxone (combination therapy)

Monitor in office for up to 2-4 hours

Re-dose in 2-4 hours if withdrawal subsides then reappears

Maximum dose for first day: 4 mg

Second Day: Adjust dose dependent on patient's experiences on first day ie withdrawal symptoms or excess sedation. Target dose 12-16 mg daily

Patients dependent on **LONG ACTING** opioids

Doses of methadone or LAAM should be decreased to a stable state of 30mg of methadone or equivalent:

Methadone 40 mg = Buprenorphine 6 mg

Methadone 60 mg = Buprenorphine 12 mg

Methadone 80 mg = Buprenorphine 16-18 mg

Begin induction 24 hours after last methadone or 48 hours after last LAAM. No additional methadone or LAAM given after induction

First Dose: 2mg sublingual Suboxone (combination therapy)

Monitor in office for up to 2-4 hours

Re-dose in 2-4 hours if withdrawal subsides then reappears

Maximum dose for first day: 4 mg

Second Day: Adjust dose dependent on patient's experiences on first day ie withdrawal symptoms or excess sedation. Target dose 12-16 mg daily

* Please note in terms of prescription practice, that some patients may have insurance plans that require a co-payment for each prescription. Therefore, daily prescription writing may turn out to be an excessive cost for the patient as opposed to a prescription for a larger number of pills. Alternatively, a practice may obtain supplies of Subutex as indicated above.

Buprenorphine-Stabilization and Follow up:

Patient should receive daily dose until stabilized. Then patient can be shifted to alternate day dosing, by increasing the dosing day by amount not received on the intervening days.

1. Urine screens should be done twice a week.
2. Non-attendance for counseling for more than two sessions in a row should trigger an automatic call from the counselor. Schedule an office visit with the physician to make sure that the patient understands that failure to follow through with counseling jeopardizes their treatment and puts them outside of "good standing".
3. Write 7 days worth of medication at a time for 2-3 months.
4. Once patient has remained compliant with counseling and physician visits, has not had any mishaps with the Suboxone, and feels ready to do so, extend the scripts to 14 days.

5. A patient may choose to take Suboxone every 2 or 3 days. The dose is doubled or tripled, depending on the time frame, and taken all at once. This is very effective in controlled settings such as family member dispensing or clinic dispensing or just patient preference.
6. After a period of time that varies with each patient but should reflect the compliance with treatment a script for 30 days may be written. Pill counts may be a useful monitoring tool at this point.
7. At the present time, there is no indication that actually testing for the presence of buprenorphine in the patient's system as might be done for Methadone, is necessary. Such a test may become available in the future but would only likely be used in specific cases when compliance is questioned and the clinical picture does not provide sufficient information.

Buprenorphine-Detoxification:

Rapid detox: (Three days or less)

Procedure is effective in suppressing withdrawal better than clonidine

Long term efficacy not well documented

Should only be done when there is a particularly compelling reason that the patient must be detoxed quickly i.e., out of country travel, imminent incarceration

Low doses of buprenorphine given 2-3 times daily

Moderate detox: 4-30 days

Few studies of buprenorphine for this time period

Better tolerated than clonidine

Long detox: more than 30 days

Not well studied but suggested that this is more efficacious than the more brief approaches

Staff Education/Training:

The use of agonist treatment, either methadone or buprenorphine is new to Vermont patients and providers. The abstinence-based treatments that have out of necessity been the state of the art treatment for opiate dependence are in many ways not compatible with agonist treatment. There are also not such extensive training requirements prior to MD's being able to prescribe new antidepressants or other psychotropic medications or antihypertensives, as there are for buprenorphine. Having buprenorphine as an office based treatment option is also new to Vermont as treatment as typically been provided at treatment centers.

This new set of circumstances offers Vermont providers an opportunity to move away from "abstinence based treatment as always" and into the use of research grounded therapies. MD's should have a clear expectation that clinicians to whom they refer their buprenorphine treated patients, will have been trained in evidence based therapies such as Cognitive Behavioral Therapy, Motivation Enhancement Therapy, DBT-S etc. Training and orientation to such therapies must include the patient for whom such treatment approaches may be new, or difficult to accept initially. Please use the ADAP office for assistance as well as the SAMSA website for additional assistance for this training.

Funding:

Insurance medication precertification is required prior to starting a patient on buprenorphine. State program approval does not automatically mean that programs will be funded. State program approval does not automatically mean that programs will be funded. Approval will be based on program's demonstration of staff experience and/or training in agonist treatments and evidence based program focus on moving patients as needed through a continuum of services and to independent functioning.

Attached is a copy of the preauthorization form for PATH.

¹ Levels of care range from ambulatory, 1:1 substance abuse counseling in conjunction with 12 Step or other community based recovery support (least restrictive) to inpatient, medically managed acute treatment (most restrictive). See ASAM level of care placement guidelines.

²Medical co-morbidities that may affect use of buprenorphine

Hepatitis B, C

Buprenorphine inhibits hepatic mitochondrial function at high concentrations

May cause elevation of transaminases, but no documentation of fulminant liver failure due solely to buprenorphine

Monitor liver enzymes levels in patients with Hepatitis, especially those on Buprenorphine/Naloxone

Warn patients not to use Buprenorphine IV

Renal Failure

Few studies available

No significant difference in kinetics of buprenorphine in patient with renal failure vs controls

No significant side effects in patients with renal failure

Medication Interactions

Cytochrome P450 3A4 Interactions

3A4 Inhibitors May Raise Buprenorphine levels

e.g.. Fluoxetine (Prozac) Fluvoxamine (Luvox), nefazodone (Serzone) cimetidine (Tagamet) and possibly antiretrovirals ie ritonavir

3A4 Substrates may raise Buprenorphine levels

e.g. Trazodone (desyrel), alprazolam (Xanax), Diazepam (Valium), buspirone (Buspar), zolipidem (Ambien) caffeine, haloperidol (Haldol), pimozone (Orap), erythromycin, nifedipine, oral contraceptives

3A4 Inducers may lower buprenorphine levels

e.g. carbamazepine, Phenobarbital, phenytoin, barbiturates, primidone, St. John's Wort, rifampin protease inhibitors (nelfinavir, lopinavir) non-nucleoside Rtiis (nevirapine, efavirenz)

A complete list of substrates, inhibitors and inducers: [www. drug-interactions.com](http://www.drug-interactions.com)

³ Staff and patient education/training program

Staff Education

Treating patient with substance abuse disorders

The disorder of opiate dependence

Role and importance of medication in treatment of opioid dependence

Maintenance of confidentiality

Treatment philosophy

Providing medication

Role of non-pharmacological treatments

Universal precautions

Patient Information

Informed consent

Treatment agreements

Appendix

DSM-IV Diagnosis of Opiate Dependence

-Maladaptive pattern of use, leading to significant impairment or distress, as manifested by 3 or more of the following, occurring at any time in the same 12-month period.

- 1.Tolerance, as defined by decreased effect with same amount or increased amount needed to achieve same effect.
- 2.Withdrawal, as defined by characteristic syndrome for the substance when withdrawn or closely related substance taken to relieve the syndrome.
- 3.An increase in the amount or the duration from what was intended.
- 4.Persistent desire or unsuccessful attempts to cut down or control use.
- 5.Spending a great deal of time in activities needed to obtain or use the substance or recover from the effects of it.
- 6.Giving up social, occupational, or recreational activities because of use.
- 7.Continuing the use despite knowing that it is causing or worsening a persistent or recurrent psychological or physical problem.

Ten Factor Office Based Criteria Check List

In general, 10 factors help determine if a patient is appropriate for office-based buprenorphine treatment. Check off "yes" or "no" next to each factor.

Factor	Yes	No
Does the patient have a <i>diagnosis of opioid dependence</i> ?		
Is the patient <i>interested in office-based buprenorphine treatment</i> ?		
Is the patient <i>aware of the other treatment options</i> ?		
Does the patient understand the <i>risks and benefits</i> of buprenorphine treatment and that it will address some aspects of the substance abuse, but not all aspects?		
Is the patient expected to be <i>reasonably compliant</i> ?		
Is the patient expected to <i>follow safety procedures</i> ?		
Is the patient <i>psychiatrically stable</i> ?		
Are the <i>psychosocial circumstances</i> of the patient stable and supportive?		
Are <i>resources available in the office</i> to provide appropriate treatment? Are there other physicians in the group practice? Are treatment programs available that will accept referral for more intensive levels of service?		
Is the patient <i>taking other medications that may interact</i> with buprenorphine, such as naltrexone, benzodiazepines, or other sedative-hypnotics?		

Information for the above guidelines was obtained in part from the following
BUPRENORPHINE CLINICAL PRACTICE GUIDELINES FIELD REVIEW DRAFT
November 17, 2000

Use of Buprenorphine in Pharmacologic Management of Opioid Dependence

Course Director: Elinore F. McCance-Katz, MD. PhD; Medical College of Virginia

Thanks to John Ross Brooklyn, MD and Todd Mandell, M.D.



Office of Vermont Health Access
312 Hurricane Lane, Suite 201
Williston, Vermont 05495
802-879-5900

Agency of Human Services

~BUPRENORPHINE ~
Prior Authorization Request Form

Vermont Medicaid has established criteria for prior authorization of buprenorphine (Suboxone®, Subutex®). These criteria are based on concerns about safety and the potential for abuse and diversion. For beneficiaries to receive coverage for this drug, prescribers must telephone or complete and fax this form to MedMetrics Health Partners. Please complete this form in its entirety and sign and date below. Incomplete requests will be returned for additional information.

Submit request via: Fax: 1-866-767-2649 or Phone: 1-800-918-7549

Prescribing physician:

Name: _____

Phone #: _____

Fax #: _____

Beneficiary:

Name: _____

Medicaid ID #: _____

Date of Birth: _____ Sex: _____

Diagnosis: _____

Pharmacy (if known): _____ Phone: _____ &/or FAX: _____

QUALIFICATIONS

MDs	Prescribers must have special 'X' DEA license in order to prescribe. Prescribers must also have the capacity to refer patients to an evidence-based substance abuse counseling and monitoring program and have no more than 30 patients on Buprenorphine.
Patients	Patients must have a diagnosis of opiate abuse confirmed. Patients must also have been advised of other treatment options, and have signed an informed consent form or treatment contract.

PROCESS

► Answer the following questions:

Has MD been oriented by OVHA Medical Director regarding buprenorphine guidelines?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If this is a new patient , is he/she free of any special considerations? These include: hepatitis, pregnancy, CAD/dual diagnosis/psych med/hx of suicidal ideation/continued substance abuse (benzo/ETOH)/hx of treatment failure, incarceration or poor psychosocial-supportive environment)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
If this is an established patient , has he/she been compliant with MD appointments?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
If this is an established patient , has he/she been referred to an evidence-based substance abuse counseling and monitoring program?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

► If all answers are YES or N/A, then fax form to MedMetrics Health Partners.

► If any answers are NQ, then you must fax this form to Dr. Strenio, OVHA Medical Director, at 802-879-5963.

If Agent, please print name: _____

Prescriber/Agent Signature: _____ **Date of request:** _____

ASAM Adult Admission Crosswalk

Dimensions	Level I Outpatient	Level II.1 Intensive Outpatient	Level II.5 Partial	III.1 Clinically Managed Low Intensity Residential	III.3 Clinically Managed High-Intensity Residential Treatment	III.5 Clinically Managed Medium Intensity Residential	III.7 Medically Monitored High Intensity Residential/inpatient	IV Medically Managed Intensive Inpatient
Dimension 1 Alcohol Intoxication and/or Withdrawal Potential	No significant withdrawal or at minimal risk for severe withdrawal	Minimal risk of severe withdrawal	Moderate risk of severe withdrawal	Not at risk of withdrawal or experiencing minimal or stable withdrawal	Not at risk of severe withdrawal	Minimal risk of severe withdrawal at III.3 or III.5 If withdrawal is present, it meets Level III.2-D	High risk of withdrawal, but manageable at Level III.7-D and not requiring full licensed hospital resources	High risk of withdrawal requiring full licensed hospital services
Dimension 2 Biomedical Conditions and Complications	None or v. stable, or patient is receiving concurrent medical monitoring	None or not a distraction from treatment. I.e. manageable at Level II.1	None or not sufficient to distract from treatment. I.e. manageable at II.5	None or stable, or patient is receiving concurrent medical monitoring	None or stable, or patient is receiving concurrent medical monitoring	None or stable, or patient is receiving concurrent medical monitoring	Needs 24 hour medical monitoring but not intensive treatment	Requires 24 hour medical and RN care
Dimension 3 Emotional, Behavioral or Cognitive	None or very stable, or patient is receiving concurrent mental health monitoring	Mild severity, with potential to distract from recovery;	Mild to moderate severity, with potential to distract from	None or minimal; not distracting to recovery	Mild to moderate severity; patient needs structure to focus on	Patient demonstrates repeated inability to control impulses or personality	Moderate severity; patient needs 24-hour structured setting	Severe and unstable problems: requires 24-hour psychiatric care with

e Conditio ns and Complic ations		patient needs monitoring	recovery. Patient needs stabilizatio n		recovery.	disorder requires structure to shape behavior		concomitant addictions treatment
Dimensi on 4 Readine ss to Change	Patient is ready for recovery but need motivating and monitoring strategies to strengthen readiness. Or, high severity in this but not other dimensions	Variable engagemen t in treatment, ambivalenc e or lack of awareness of the substance use or mental health problem. Requires structured program several times a week to promote progress	Poor engagemen t in treatment, ambivalenc e or lack of awareness of CD or mental health problems: requires near-daily structured program or intensive engagemen t.	Patient open to recovery, but needs structured environmen t to maintain therapeutic gains.	Little awareness and needs interventio ns only available at Level III.3 to engage and stay in treatment -or- High severity in this dimension but no in others	Marked difficulty with or opposition to treatment with dangerous consequence s. -or- High severity in this dimension but no in others	High resistance and poor impulse control, despite negative consequences . Needs motivating strategies only available in a 24 hour structured setting	Problems in this dimension do not qualify for Level IV services

Dimensions	Level I Outpatient	Level II.1 Intensive Outpatient	Level II.5 Partial	III.1 Clinically Managed Low Intensity Residential	III.3 Clinically Managed Medium Intensity Residential	III.5 Clinically Managed High Intensity Residential	III.7 Medically Monitored Intensive Inpatient	IV Medically Managed Intensive Inpatient
Dimension 5 Relapse, Continued Use or Continued Problem Potential	Able to maintain abstinence or control use and pursue recovery or motivational goals with minimal support	Intensification of addition or mental health symptoms indicate high likelihood of continued problems/use without close monitoring and support several times weekly	Intensification of addiction or mental health symptoms despite active participation in Level I or II.1: high likelihood of relapse, continued use or problems without near-daily monitoring and support	Patient understands relapse but needs structure to maintain therapeutic gains	Little awareness and needs interventions available only at Level III.3 to prevent continued use, with imminent dangerous consequences due to cognitive deficits or comparable dysfunction	No recognition of the skills needed to prevent continued use with imminent dangerous consequences	Unable to control use, with imminently dangerous consequences despite active participation at less intensive levels of care.	Problems in this dimension do not qualify for Level IV services
Dimension 6 Recovery Environment	Recovery environment is supportive and/or patient has skills to cope	Recovery environment is not supportive but patient can cope given structure and	Recovery environment not supportive but with structure, support and relief from home,	Environment is dangerous but recovery is achievable if this level is available.	Environment is dangerous and patient needs 24 hour structure to learn to cope	Environment is dangerous and patient lacks skills to cope outside of a highly structured 24 hour setting	Environment is dangerous and patient lacks skills to cope outside of a highly structured 24 hour setting	Problems in this dimension do not qualify for Level IV services

		supports	patient can cope.					
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ASAM Patient Placement Criteria, Second Edition-Revised (adapted for PrimariLink use, T. W. Mandell, M.D. 2002)

1. How do I find a doctor who prescribes buprenorphine for the treatment of opioid addiction?

Doctors in each State who have waivers to prescribe buprenorphine for the treatment of opioid addiction are listed on the [SAMHSA Buprenorphine Physician Locator](#) Web site.

[-top-](#)

2. Can buprenorphine be used to treat addiction to prescription pain relievers, such as oxycodone or codeine?

Prescription pain relievers like oxycodone and codeine are opioids. Buprenorphine is used to treat addiction to opioids. Buprenorphine prevents withdrawal symptoms so that a person can stop taking the opioid drug to which he or she is addicted. A doctor who is qualified in the use of buprenorphine can determine if it is a good choice for a patient who is addicted to opioid pain relievers.

Doctors in each State who have waivers to prescribe buprenorphine for the treatment of opioid addiction are listed on the [SAMHSA Buprenorphine Physician Locator](#) Web site.

[-top-](#)

3. Can Buprenex®, or any other medications besides Subutex® and Suboxone®, be prescribed/dispensed for opioid addiction treatment in practice settings other than Opioid Treatment Programs (OTPs) (i.e., methadone clinics)?

No. At the present time Subutex® and Suboxone® are the only Schedule III, IV, or V substances to have received Food and Drug Administration approval for opioid addiction treatment. Thus, they are the only opioid medications that may be prescribed or dispensed for this indication outside the OTP setting. The approval of Subutex® and Suboxone® does not affect the status of any other medications. Buprenex® is not approved for treatment of opioid addiction. The status of methadone and LAAM are also unchanged. They still can be only dispensed, not prescribed, for opioid addiction, and only at Federally regulated OTPs.

[-top-](#)

4. I submitted my waiver notification to SAMHSA a few weeks ago and received an acknowledgment letter, but I haven't heard anything since. How can I check on the status of my waiver?

If you have submitted a notification and received an acknowledgment letter (or e-mail) from us, then your notification is under active review. It is SAMHSA's intent to complete the review of notifications within 45 days of receipt. When processing of your notification is complete, we will mail you a letter confirming your waiver and containing your prescribing identification number.

If you have submitted a notification and received an acknowledgment from us, and it has been more than 2 months since you submitted your notification, OR if you submitted a notification and you did not receive an acknowledgment from us that it had been received, please call 1-866-BUP-CSAT (1-866-287-2728) or e-mail info@buprenorphine.samhsa.gov. Please be prepared to provide the date when you submitted your original notification and other identifying information.

[-top-](#)

5. I am a waived physician and would like to add, change, or remove my listing on the SAMHSA Buprenorphine Physician Locator Web site. How do I do this?

Waived physicians may call 1-866-BUP-CSAT (1-866-287-2728) or e-mail info@buprenorphine.samhsa.gov with requests to change [Locator](#) listings.

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6. I am a waived physician, and I've moved my practice location since receiving my waiver. Do I need to notify SAMHSA or DEA of my new practice address?

Waived physicians who change the primary practice address at which they intend to treat opioid addiction under the authority of their DATA 2000 waiver must notify SAMHSA by calling 1-866-BUP-CSAT (1-866-287-2728) or via e-mail at info@buprenorphine.samhsa.gov. The Drug Enforcement Administration must also be notified. Call the DEA Office of Diversion Control at 1-800-882-9539. Phone numbers for local DEA offices can be found on the DEA Web site at <http://www.dea.gov>.

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7. With a DATA 2000 waiver, can I *prescribe* Subutex® or Suboxone® for opioid addiction in more than one practice location? Can I *dispense* Subutex® or Suboxone® from more than one location?

Physicians with DATA 2000 waivers may prescribe Subutex® or Suboxone® for opioid addiction in any appropriate practice setting in which they are otherwise credentialed to practice (e.g., office, hospital). However, they may store and dispense Subutex® or Suboxone® (or any other controlled substances) only at the practice address(es) that they have registered with the DEA. Only one DATA-waiver unique identification number will be issued for each DATA-waived physician, no matter how many practice locations or DEA registrations a physician may have.

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8. I've heard this new model for the treatment of opioid addiction referred to as "office-based opioid therapy." Does that mean that physicians with DATA 2000 waivers can use Subutex® and Suboxone® to treat opioid addiction only in the office-based setting?

No. Treatment of opioid addiction under the authority of a DATA 2000 waiver is not confined to the office-based setting. Physicians with DATA 2000 waivers may treat opioid addiction with Subutex® and Suboxone® in any practice settings in which they are otherwise credentialed to practice and in which such treatment would be medically appropriate (e.g., office, community hospital, health department).

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9. Are there specific Federal record keeping requirements for office-based opioid therapy?

DEA record keeping requirements for office-based opioid therapy go beyond the Schedule III record keeping requirements. According to DEA:

Practitioners must keep records (including an inventory that accounts for amounts received and amounts dispensed) for all controlled substances dispensed, including Subutex and

Suboxone (21 PART 1304.03[b]). In some cases, patients return to the prescribing physician with their filled Subutex or Suboxone prescriptions so that the practitioner can monitor the induction process. While it is acceptable for the patient to return to the practitioner with their filled prescription supplies, practitioners shall not store and dispense controlled substances that are the result of filled patient prescriptions.

Practitioners must keep records for controlled substances prescribed and dispensed to patients for maintenance or detoxification treatment (21 CFR Section 1304.03[c]). Many practitioners comply with this requirement by creating a log that identifies the patient (an ID number may be used instead of name), the name of the drug prescribed or dispensed, as well as the strength and quantity and date of issuance or dispensing. Some physicians comply with this requirement by keeping a copy of the prescription in the patient record.

Alternatively, DEA suggests that practitioners could keep separate records for controlled substances prescribed and dispensed for maintenance or detoxification treatment to facilitate the record reviews during physician inspections for DATA compliance. This way, DEA will only review those records related to controlled substances prescribed and dispensed for maintenance or detoxification treatment for physicians maintaining separate records.

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10. Does DATA 2000 limit the number of patients who may be treated for opioid addiction at any one time by a physician group practice?

The physician group practice limit was eliminated by Public Law 109-56. Effective August 2, 2005, physicians in group practices, just like physicians who are not in group practices, are permitted to treat up to 30 patients each at any given time.

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11. Is there a limit on the number of patients a practitioner may treat with buprenorphine at any one time?

Yes, DATA 2000 specifies that an individual physician may have a maximum of 30 patients on opioid therapy at any one time. SAMHSA intends to issue a notice of proposed rulemaking that will modify the individual physician patient limits.

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12. Can an Opioid Treatment Program (i.e., methadone clinic or OTP) dispense Subutex® and Suboxone® to patients admitted to the program? If so, is there a limit on the number of patients who can be treated with Subutex® and Suboxone® for opioid addiction treatment in an OTP? Is a DATA 2000 waiver required?

New SAMHSA regulations permit OTPs serving persons addicted to prescription opioids or heroin to offer buprenorphine treatment along with methadone and ORLAAM®. These regulations enable OTPs that are certified by SAMHSA to use Subutex® and Suboxone® for opioid maintenance or detoxification treatment. [Click here to read the text of the Federal regulation](#) (PDF, 43 kb).

The provision of opioid addiction treatment with Subutex® and Suboxone® in OTPs certified by SAMHSA/CSAT does not require a DATA 2000 waiver. Additionally, such treatment is not subject to the 30-patient limit that applies to individual physicians and group practices providing opioid addiction treatment outside the OTP system under the authority of a DATA 2000 waiver. The provision of opioid addiction treatment with Subutex® or Suboxone® in treatment settings other than OTPs, even by physicians who are licensed to practice in

OTPs, does require a DATA 2000 waiver and is subject to the 30-patient limit for individual physicians and group practices.

OTP's providing Subutex® and Suboxone® for opioid maintenance or detoxification treatment must conform to the Federal opioid treatment standards set forth under 42 C.F.R. § 8.12. These regulations require that OTPs provide medical, counseling, drug abuse testing, and other services to patients admitted to treatment. To offer Subutex® and Suboxone®, OTPs will need to review their State licensing laws and regulations and to modify their registration with the DEA to add Schedule III narcotics to their registration certificates. Opioid treatment programs can initiate this streamlined process by fax or letter. The letter should include the OTP's DEA registration number and request that the registration be amended to list Schedule III narcotic drugs. The letter must be signed by the Program Sponsor (Program Director) or Medical Director. The completed letter can be either faxed to Ms. Ghana Giles at 202-353-1125 or mailed to Ms. Giles at: DEA, Registration Unit - OPRR, Washington, DC, 20537. In addition, OTPs can access the [DEA registration Web site](#) for more information.

Once the registration has been modified, OTPs can order Subutex® and Suboxone® directly from Reckitt Benckiser, the product manufacturer, by calling 1-877-782-6966.

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13. Can the medical personnel in correctional facilities dispense (or administer) buprenorphine to incarcerated individuals?

Qualified physicians who have obtained a DATA 2000 waiver can dispense or prescribe Subutex® or Suboxone® for addiction treatment in any practice setting, including in correctional facilities. Currently, State laws and policies vary considerably regarding opioid-assisted (methadone) treatment within correctional facilities. It is assumed that this same variation will occur with the use of buprenorphine in this setting. The 30-patient limit per waived physician or group practice as stated in the DATA 2000 legislation also applies to the prescribing or dispensing of this treatment in correctional facilities.

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14. Can physicians and other authorized hospital staff administer buprenorphine to a patient who is addicted to opioids but who is admitted to a hospital for a condition other than opioid addiction?

Neither the Controlled Substances Act (as amended by the Drug Addiction Treatment Act of 2000) nor DEA implementing regulations (21 CFR 1306.07(c)) impose any limitations on a physician or other authorized hospital staff to maintain or detoxify a person with an opioid treatment drug like buprenorphine as an incidental adjunct to medical or surgical conditions other than opioid addiction.

Thus, a patient with opioid addiction who is admitted to a hospital for a primary medical problem other than opioid addiction, e.g., myocardial infarction, may be administered opioid agonist medications (e.g., methadone, buprenorphine) to prevent opioid withdrawal that would complicate the primary medical problem. A DATA 2000 waiver is not required in order to prescribe or dispense buprenorphine (or methadone) in this circumstance. It is good practice for the admitting physician to consult with the patient's addiction treatment provider, when possible, to obtain treatment history.

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15. Can Physician Assistants or Nurse Practitioners prescribe buprenorphine for opioid addiction treatment in States that permit them to prescribe Schedule III, IV, or V

medications?

No. Under DATA 2000, waivers to permit the prescription of Schedule III, IV, or V medications for opioid addiction treatment are available only to "qualifying physicians." The term "qualifying physician" is specifically defined in DATA 2000 as a "physician who is licensed under State law," has DEA registration to dispense controlled substances, has the capacity to refer patients for counseling and ancillary services, will treat no more than 30 such patients at any one time, and is qualified by certification, training, and/or experience to treat opioid addiction.

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16. May physicians in residency training programs obtain DATA waivers?

The DATA legislation does not specify that a physician in a residency training program who otherwise meets the qualifications for a DATA waiver is ineligible to apply for and obtain a waiver. Therefore, SAMHSA has granted DATA waivers to physicians in residency training who have unrestricted licenses and the appropriate DEA registration. Individual States may have laws with more restrictive rules regarding who may prescribe or dispense Schedule III narcotic drugs for detoxification or maintenance treatment.

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17. Where can I get a copy of the *Buprenorphine Clinical Practice Guidelines*?

Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction, Treatment Improvement Protocol (TIP) 40, is available via [SAMHSA's National Clearinghouse for Alcohol and Drug Information \(NCADI\)](#), or by calling 1-800-729-6686. It will also be available in the near future from the [National Library of Medicine \(NLM\)](#), or by calling 1-888-346-3656.

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18. Are Subutex® and Suboxone® available in pharmacies?

Subutex® and Suboxone® are available in pharmacies throughout the United States. Pharmacies and physicians can obtain the medications by contacting a pharmaceutical wholesaler directly, or by contacting the drug manufacturer, Reckitt Benckiser, at 1-877-782-6966. Consumers may also call the same toll-free number for additional information.

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19. Do pharmacies need waivers to dispense buprenorphine?

No. Physicians are required to obtain DATA 2000 waivers to prescribe and dispense buprenorphine (Subutex® and Suboxone®) for opioid addiction, but pharmacists and pharmacies are not required to have any special credentials for dispensing these medications above and beyond those for other Schedule III medications. Certain Federal laws and regulations, however, do affect pharmacy practice with regard to opioid addiction treatment prescriptions.

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20. How can a pharmacist verify if a physician has a waiver to prescribe buprenorphine (Subutex® or Suboxone®) for the treatment of opioid addiction?

Effective July 25, 2005, physicians must include their DATA 2000 waiver ID number on prescriptions for opioid addiction treatment medications. The practitioner's DEA registration number and the unique identification number (DATA 2000 waiver ID number or "X" number) must be on the prescription 21 CFR 1306.05(a). The identification number is not in lieu of the DEA registration number, it is an addition. If the prescription is telephoned to the pharmacy, the pharmacist must have both of these numbers on the prescription record so the physician can provide the numbers or the pharmacist may have them on file.

The [SAMHSA Buprenorphine Physician Locator](#) Web site lists the physicians in each State who have DATA 2000 waivers. A physician listed on the site can be considered to have a valid DATA 2000 waiver. **Note, however, that the site does not list every physician with a valid waiver, only those who have agreed to be listed on the site.** Physicians with valid waivers may choose not to be listed on the site.

A pharmacist desiring to verify that a physician who is not listed on the site has a valid DATA 2000 waiver can contact SAMHSA by phone at 240-276-2716 or by e-mail at Nicholas.Reuter@samhsa.hhs.gov. Pharmacists should convey their DEA registration number with these requests.

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21. Can Subutex® or Suboxone® be prescribed for conditions other than opioid addiction, e.g., pain control?

Subutex® and Suboxone® have received FDA approval only for the treatment of opioid addiction. However, once approved, a drug product may be prescribed by a licensed physician for any use that, based on the physician's professional opinion, is deemed to be appropriate. Neither the FDA nor the Federal government regulates the practice of medicine. Any approved product may be used by a licensed practitioner for uses other than those stated in the product label. Off-label use is not illegal, but it means that the data to support that use has not been independently reviewed by the FDA. Information on FDA policy regarding off-label use of pharmaceuticals is available on the FDA Web site, <http://www.fda.gov/cder/cancer/tour.htm>, or <http://www.fda.gov/cder/present/diamontreal/regappr/index.htm>

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22. Can buprenorphine be used to treat cocaine addiction?

Cocaine is not an opioid drug. According to the approved product labeling, Suboxone® and Subutex® are indicated for the treatment of opioid addiction. In addition, under DATA 2000, codified at 21 U.S.C. 823(g), prescription use of Suboxone® and Subutex® in the treatment of opioid addiction is limited to physicians who meet certain qualifying requirements, and have notified the Secretary of Health and Human Services (HHS) of their intent to prescribe this product for the treatment of opioid addiction.

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23. Can a person currently being treated with methadone switch to buprenorphine without suffering withdrawal symptoms?

Patients can switch from methadone to buprenorphine treatment, but because the two drugs are very different, patients are not always satisfied with the results. A number of factors affect whether buprenorphine is a good choice for someone who is currently receiving methadone. It is also possible for patients receiving buprenorphine to be switched to methadone. Patients

interested in finding out more about the possibility of switching treatment should discuss this with the doctor who is prescribing their medication.

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24. How much will a dose of buprenorphine cost a consumer?

The final cost to consumers of prescribed outpatient medication such as buprenorphine is determined by several parties: the pharmaceutical manufacturer, the insurer, the health plan (if any) or prescribing clinic, and finally, by the retail pharmacies that typically dispense the medication. It is important to note that the cost of buprenorphine itself is only one part of the cost of outpatient opioid treatment, which also includes the cost of each physician visit, any charges for laboratory analyses or emergency detoxification or stabilization, and any necessary ongoing service referrals and visits that are determined by the physician who prescribes the medication.

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25. Will Medicare and Medicaid cover substance abuse treatment and buprenorphine?

Medicare – Substance abuse treatment may be covered under Medicare if it is determined to be medically necessary and it is provided in an inpatient or outpatient treatment center that is Medicare-certified according to the HHS. Medicare does not generally cover prescription drugs that are prescribed or dispensed to individuals on an outpatient basis. If buprenorphine is administered by a Medicare-certified facility as a component of inpatient or emergency treatment such as detoxification or early stage stabilization treatment, rather than being a separate outpatient prescription, the medication's cost could be covered during that episode of care, just as the cost for any other medication used in the treatment process is covered when administered within a certified program/facility. However, this reimbursement would only occur if the Medicare-certified facility had buprenorphine on its list of eligible drugs and if the patient received the treatment at the facility.

There is currently no Medicare fee-for-service coverage for buprenorphine prescribed by a physician during an outpatient office visit, whether for outpatient detoxification, early stabilization, or maintenance. However, if a person is covered by a Medicare HMO that has a substance abuse and a pharmacy benefit, buprenorphine could be covered if it is on that particular plan's formulary and is determined to be medically necessary under the plan's coverage policies. Additionally, some Medicare beneficiaries have Medicare supplementary or Medi-gap insurance that covers some pharmaceutical benefits. Again, however, even under a supplementary plan, there may or may not be benefits for substance abuse treatment or for buprenorphine if it is not on the supplementary insurer's formulary. Medicare HMO members should read their coverage bulletins or call their plans to determine whether they have coverage for buprenorphine and for substance abuse treatment. Many HMOs do not cover outpatient substance abuse treatment except on an emergency basis required by law.

Medicaid – Medicaid coverage of substance abuse treatment and medication such as buprenorphine varies considerably by State and by whether or not the State's Medicaid plan is offered under managed care/HMO arrangements. Coverage of buprenorphine and/or substance abuse treatment connected with buprenorphine under Medicaid benefits will not only be a State-by-State decision, but will also be subject in most States to rules about prior authorization and medical necessity. In addition, in many States, Medicaid programs operate with a preferred drug list on which buprenorphine must be placed before it can be reimbursed. State Medicaid programs administered by HMOs may have an additional level of formulary and treatment authorization that affects whether or not buprenorphine, and treatment connected to it, is covered.

26. Will buprenorphine be available in treatment programs for indigent patients and patients who don't have Medicaid or Medicare?

Community health centers, clinics, and hospitals offering free care to indigent individuals may or may not make buprenorphine available. Availability will depend on whether or not that health center or hospital offers substance abuse treatment or emergency care of addictions and whether or not buprenorphine is available on its formulary, as well as whether there is a staff/attending physician associated with the hospital who is qualified to administer the drug and whether the medication is determined to be medically necessary.

Individuals not eligible for Medicaid or Medicare who are not indigent fall into two categories: those who have commercial insurance coverage and those who do not. If an individual has insurance coverage outside of Medicare and Medicaid, the individual's insurance plan may or may not cover all or part of buprenorphine medication, depending on medical necessity, whether or not pharmaceuticals are covered, whether or not there is a required co-payment, and whether or not buprenorphine is on the plan's approved drug list. Individuals who are not insured but who are neither indigent nor eligible for Medicaid or Medicare will have to pay themselves for buprenorphine and any treatment associated with it.

27. Where can I find out more information about buprenorphine treatment for opioid addiction?

In addition to this Web site, you can visit the FDA's buprenorphine pages at http://www.fda.gov/cder/drug/infopage/subutex_suboxone/default.htm, and the manufacturer's Web site at <http://www.suboxone.com/>.

Additionally, you can contact the SAMHSA Buprenorphine Information Center by telephone, toll-free at 1-866-BUP-CSAT (1-866-287-2728), or by e-mail at info@buprenorphine.samhsa.gov.

28. As a physician employed by the Federal Government (Veterans Administration, Indian Health Service, Federal Department of Corrections, etc.) practicing in a Federal Government installation, am I eligible for a DATA 2000 waiver?

Yes. Physicians employed by an agency of the Federal Government are eligible for DATA 2000 waivers. In order to be eligible for a waiver under DATA 2000, a physician must have a valid, individually assigned DEA registration number (in addition to a license to practice medicine and the credentialing/training discussed elsewhere). A physician who is directly employed by the Federal Government may obtain a DEA number, free of charge, without being licensed in the state where the Federal facility is located (the physician must have a valid state license in one of the 50 states, the District of Columbia, Virgin Islands or Puerto Rico). In order to receive a DEA number under this program, each physician must complete a DEA registration application that includes the physician's official business address and the name and phone number of the certifying official who can verify the physicians' eligibility for this program. This DEA registration number may only be used for practice within the Federal Government installation and may not be used for practice outside this setting.

In addition to this Web site, you can visit the Food and Drug Administration's buprenorphine pages at http://www.fda.gov/cder/drug/infopage/subutex_suboxone/default.htm, and the manufacturer's Web site at <http://www.suboxone.com/>.

Additionally, you can contact the SAMHSA Buprenorphine Information Center toll-free at 1-866-BUP-CSAT (1-866-287-2728), or by e-mail at info@buprenorphine.samhsa.gov.